UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation *This Document Relates to All Actions*	Case No. 19-md-02875 (RBK/KW)

LOSARTAN AND IRBESARTAN PLAINTIFFS' REQUESTS FOR PRODUCTION OF DOCUMENTS TO RETAIL PHARMACY DEFENDANTS

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, Plaintiffs propound the following requests upon each Retail Pharmacy Defendant.[1] These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

The requests that follow track the Court-Approved Requests for Production to be answered by the Retail Pharmacy Defendants for Valsartan.[2] The Retail Pharmacy Defendants have previously advised, and Plaintiffs understand, that there remain differences in the ability of each Retail Pharmacy Defendant to respond to the requests below, including differences in what data is

[1] To the extent it applies these requests are made in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Orders on macro discovery issues filed on November 25, 2019.

[2] To the extent it applies, each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the November 25, 2019 Order on macro discovery issues pertaining to the Manufacturing Defendants (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral and/or written rulings following the December 11, 2019 discovery hearing, the January 15, 2020 discovery hearing, the January 28, 2020 discovery conference, the February 13, 2020 discovery conference, and the July 6, 2020 macro discovery hearing.

available, and in the type and extent of data that is available in a reasonably accessible format. Following service of these requests for production, each Retail Pharmacy Defendant shall serve its own individual responses to the requests set forth below, including identification of any specific issues that the Retail Pharmacy Defendant has with the requests. The parties will meet and confer in good faith on the substance of any such responses, to the extent necessary, and to address any deficiencies or Plaintiffs' reasonable questions regarding Retail Pharmacy Defendants' responses.

DEFINITIONS

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"API Manufacturer" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for losartan or irbesartan.

"Finished Dose Manufacturer" includes any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of losartan or irbesartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Manufacturer Defendants" includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation (including attachments to mails), whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof.

This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests, "Documents" shall refer only to centrally stored,

noncustodial data maintained by the retailer pharmacy in the ordinary course of business and available via reasonable search of available records and in a reasonably accessible format, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2011 through December 31, 2019.

"Retail Pharmacy Defendants" refers to any and all entities listed by name as "Retail Pharmacy Defendants" in Plaintiffs' Master Complaints, including any agents or predecessor entities.

"TPP" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors, and any other health benefit provider in the United States of America and its territories.

"Losartan" or "LCDs" means any drug with losartan as an active ingredient. For purposes of these Requests, "Losartan" or "LCDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Irbesartan" or "ICDs" means any drug with irbesartan as an active ingredient. For purposes of these Requests, "Irbesartan" or "ICDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Recalled Product" means any drug with losartan or irbesartan as an active ingredient, as well as all finished drug formulations of losartan or irbesartan, including any losartan-containing drug or irbesartan-containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Retail Pharmacy Defendant(s) in the ordinary course of business.

"You," "your" or "defendant" shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Chain Security Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Wholesaler Defendants" refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs' Master Complaints, including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

INSTRUCTIONS

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED

I. SOURCING (UPSTREAM)

1. Documents sufficient to identify the ICDs and LCDs purchased by you during the relevant time period, including quantity/units, dates of purchase, NDC, supplier, expiration date, and batch and/or lot number. In the alternative, Plaintiffs would accept a sworn response in the following table:

Date of Purchase	NDC Code	Lot or Batch Number	Expiration Date	Finished Dose Manufacturer	API Manufacturer	Entity Product was Purchased From	Price Per Pill	Pill Quantity Purchased	Number of Pills Subject to Recall	Number of Pulls Recovered in Any Recall	State Where Wills Were Dispensed

2. Documents sufficient to identify as exemplar the ordinary-course transactional documents accompanying ICDs or LCDs purchased by you (e.g., invoices, bills of lading, packing slips, etc.).

II. SALES (DOWNSTREAM)

3. Documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling information for ICDs or LCDs dispensed by you.

4. Documents sufficient to identify your sale of ICDs or LCDs to consumers, in either of the forms identified in Requests 4(a) and 4(b), below. You need only produce this information in one of these formats.

   a. Documents sufficient to identify the quantities/units and number of purchasers of ICDs or LCDs dispensed by you, by month, state/territory, expiration date, and NDC, as well as by batch and/or lot number.

   b. Documents sufficient to identify when and to whom you dispensed ICDs LCDs, including quantity/units, NDC, expiration date, and batch, and/or lot number, to be produced in an anonymized manner. You also may redact protected patient information to address any privacy or HIPAA concerns raised by the production of this data, as appropriate.

   c. In the alternative, Plaintiffs will accept a sworn response with the following information:

Date of Sale	NDC Code	Lot or Batch Number	Expiration Date	Finished Dose Manufacturer	API Manufacturer	Entity Product was Purchased From	Price Per Pill	Pill Quantity Sold	Number of Pills Subject to Recall	Number of Pulls Recovered in Any Recall	State Where Wills Were Dispensed

5. The amount paid by consumers for ICDs and LCDs dispensed by you identified in Request No. 4, to be produced in an anonymized manner. You also may redact protected patient information to address any privacy or HIPAA concerns raised by the production of this data, as appropriate.

III. WARRANTIES/STATEMENTS (UPSTREAM)

6. Documents sufficient to show your final written policies or procedures for the types of documents or other information to be provided by a prospective supplier and/or manufacturer of LCDs or ICDs purchased by you.

7. Documents sufficient to show the information provided to you by the Manufacturer Defendants or Wholesaler Defendants from which you actually purchased LCDs or ICDs.

IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

8. Documents sufficient to show your final written policies for the types of documents or other information and materials to be provided by you (whether such materials were created by you or not) when you dispensed LCDs or ICDs to consumers.

9. Documents sufficient to show your final written policies for the types of documents or other information and materials provided to TPPs for LCDs or ICDs dispensed by you.

V. TESTING/INSPECTION

10. Testing (if any) you performed for LCDs, and results thereof.

VI. DISTRIBUTION CENTERS

11. Documents sufficient to identify your distribution centers from which LCDs or ICDs were shipped, including location and state(s) of locations served by each distribution center.

12. To the extent available, documents sufficient to identify your distribution centers that would have received or shipped LCDs or ICDs subject to recall.

VII. RECALL

13. Documents sufficient to show the final written policies or procedures specifically governing the LCD or ICD recalls, if any.

14. Documents sufficient to show the initial LCD or ICD recall communications you received from the Manufacturer Defendant or Wholesaler Defendant from whom you purchased LCDs.

15. Documents sufficient to show the official notice by which you communicated any LCD or ICD recall implemented by you to consumers or TPPs.

16. Documents sufficient to identify (by NDC, and by lot and/or batch information to the extent maintained by you in the ordinary course of business) Recalled LCDs or ICDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.

17. Documents sufficient to show a list of your warehouse and/or distribution facilities involved in any LCD or ICD recalls.

18. Documents sufficient to show how your retail or other locations which dispensed LCDs or ICDs de-stock Recalled LCDs or ICDs.

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

19. Documents sufficient to identify your final written policy(ies) or procedures used by you to track purchases and sales of prescription drugs pursuant to the Drug Supply Chain Security Act and regulations promulgated thereunder and/or final written policy(ies) or procedures used by you to track purchases and sales of prescription drugs after January 1, 2011, and prior to the enactment of the DSCSA.

20. Documents that identify changes in written policies and procedures and the reasons for those changes.

IX. DOCUMENT PRESERVATION

21. Produce the final document/data retention or destruction policies, or sections thereof, pertinent to the documents/data called for by the above requests.

22. Produce documents that reference changes to the final document/data retention or destruction policies, or sections thereof, and the reasons for those changes.

X. COMPLAINTS

23. Produce documents sufficient to show all complaints you received from anyone concerning the purity or contamination of ICDs or LCDs during the time period from January 1, 2011 to December 31, 2019.

XI. INDEMNITY AGREEMENTS

24. Produce all final written indemnity agreements that you have with any LCD supplier from whom you purchased the LCDs at issue in this litigation. You may redact other competitive or sensitive information from the agreement, including information regarding the pricing and volume of your purchases, provided that the indemnity provision is not redacted.

XII. INSURANCE POLICIES

25. Produce all insurance policies which provide or may provide coverage for this action.

XIII. SALES AND PROFITS

26. Documents setting forth: (1) the sale price of all LCD and ICD pills, individually and in batches, lots, or other quantities utilized, (2) the profits to answering Defendant after deduction of any applicable expenses or costs, (3) any reimbursements, rebates, or subsidies provided to or from any person or entity in connection with the LCD and ICD pills.

Dated: May 22, 2023

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CERTIFICATE OF SERVICE

I certify that on the 22nd day of May 2023, I electronically transmitted the attached document to counsel of record in the above-captioned case.

/s/ Marlene J. Goldenberg
Marlene J. Goldenberg